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Dated: July 15, 2010
Electronic Signature for: Amy E. Mandragouras, Esq.: /Amy E. Mandragouras/

Docket No.: EISN-018US
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Roch Boivin *et al.*

Application No.: 10/507,067

Confirmation No.: 8892

Filed: November 10, 2004

Art Unit: 1626

For: MACROCYCLIC COMPOUNDS USEFUL AS
PHARMACEUTICALS

Examiner: S. Young

MS Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT UNDER 37 CFR § 1.705(b)(2)

Dear Sir:

1. This statement is respectfully submitted in support of the “Application for Patent Term Adjustment Including Request for Reconsideration Under 37 CFR §1.705(b)” for the above-referenced application. In view of the following, it is respectfully requested that Applicants be granted a minimum patent term adjustment of 1265 days.

2. The patent term adjustment as shown on the face of the Notice of Allowance, mailed on April 15, 2010 is 291 days. A copy of the PTO’s Patent Term Adjustment calculation (“PTA Sheet”) available on PAIR is also submitted herewith as Appendix A. Applicants respectfully submit that the determination of 291 days of patent term adjustment is incorrect for the reasons discussed below.

3. The factual bases for the above adjustment are set forth as follows:

A. Examination Delays Pursuant to 37 CFR §1.702 and §1.703

Pursuant to 37 CFR §1.703(f), the period of adjustment of the term of the patent under §1.702 is the sum of the periods of examination delay calculated under subparagraphs (a)-(e), to the extent that such periods are not overlapping, less the sum of the periods calculated under §1.704 (the period of Applicant Delay). In the above-referenced application, Applicants are entitled to a period of examination delay equal to the sum of the periods of delay under §1.703(a) and (b) for the reasons set forth below.

(i) “14 Month Delay” Pursuant to §1.703(a)(1)

In accordance with 37 CFR §1.703(a)(1), Applicants are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. 132 not later than 14 months after the date on which the requirements of 35 U.S.C. 371 were fulfilled (*i.e.*, January 10, 2006).

The Office mailed a Restriction Requirement on May 1, 2007. Accordingly, Applicants are entitled to a period of patent term adjustment beginning January 10, 2006 and ending on May 1, 2007, the date of mailing of the Restriction Requirement that was ultimately entered in the application. As such, the period of patent term adjustment due to the 14 Month Delay by the Office is **476 days**.

(ii) “4 Month PTO Response to Patentee Reply” Pursuant to 37 CFR 1.702(a)(2)

The Office has determined that 51 days of delay were accrued by the Office in the period beginning October 23, 2009 and ending on April 15, 2010. Applicants believe that the determination of this delay was erroneous. Under 37 CFR §1.703(a)(3), the Office is required to mail either an action under 35 U.S.C. 132, or a Notice of Allowance under 35 U.S.C. 151, within four months after the date of receipt of a reply in compliance with 37 CFR §1.113(c). Applicants submit that the Notice of Allowance of April 15, 2010 was issued within four months of the Notice of Appeal of December 18, 2009, and therefore the requirement is satisfied.

(iii) “Three Years Delay” Pursuant to 37 CFR §1.703(b)

The USPTO’s Determination of Patent Term Adjustment Under 35 U.S.C. 154(b) mailed on April 15, 2010 states that “If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 291 day(s).” Applicants assert that this statement by the USPTO is not correct.

The Office did not comply with the requirement of 35 U.S.C. 154(b) and 37 CFR §1.702(b), which requires issuance of a patent within 3 years after the date on which the national stage commenced under 35 U.S.C. 371(b). In accordance with 37 CFR §1.703, Applicants have calculated a maximum period of Three Years Delay (based on the above USPTO statement) beginning on the day after the date that is three years after the date on which the above-referenced patent was filed (*i.e.*, September 9, 2007), and ending on the date that the patent is expected to issue. The Notice of Allowance states that the patent is expected to issue on the Tuesday immediately preceding the date that is 28 weeks from the mailing date of the Notice of Allowance (*i.e.*, October 26, 2010). Therefore, the period of Three Years Delay is at least equal to the sum of the number of days in the period beginning on September 9, 2007 and ending on October 26, 2010. This period of delay is 1143 days. Applicants reserve the right to pursue additional Patent Term Adjustment if, for example, the patent issues after October 26, 2010. Applicants note that a Notice of Appeal was filed on December 18, 2009, but that an Appeal Brief was not filed. Accordingly, Applicants believe that no exclusion of delay was incurred under 37 CFR §1.703(b)(4).

(iv) Calculation of Total Period of Examination Delay Pursuant to 37 CFR §1.703(f)

As set forth in 37 CFR §1.703(f), the period of examination delay based on the grounds set forth in 37 CFR §1.702 is the sum of the period of 14 Month Delay (476 days, ending May 1, 2007), and the period of Three Years Delay (1143 days, beginning on September 9, 2007).

These periods of delay do not overlap. Accordingly, the total examination delay is 1619 days.

B. “Applicant Delay” Pursuant to 37 CFR §1.704

Pursuant to 37 CFR §1.704, the period of adjustment of the term of the patent due to examination delay is reduced by the period of Applicant Delay. Applicants respectfully submit

that the correct period of Applicant Delay is 354 days and seek correction based on the following remarks.

(i) Reply Having Omission

Applicants respectfully submit that a period of Applicant Delay of 118 days accrued for the submission of a Non-Compliant Response after Non-Final Office Action of February 19, 2008. This Non-Compliant Response is considered a “reply having an omission.” Therefore, pursuant to 37 CFR §1.704(c)(7), the period of adjustment shall be reduced by the number of days beginning on the day after the date the reply having an omission was filed (*i.e.*, February 19, 2008) and ending on the date that the reply correcting the omission was filed (*i.e.*, June 16, 2008), or 118 days. Accordingly, this 118 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(ii) Applicant Delay for Filing Supplemental Papers

Applicants note that the PTA sheet indicates that a period of Applicant Delay of 21 days accrued for the period beginning on the date after the filing of the Amendment after Final Action on October 23, 2009, and ending on the date of filing of the Supplemental Amendment after Final Action on November 13, 2009. Applicants further note that the application was placed in condition for allowance by the Supplemental Amendment. Accordingly, no Applicant Delay accrued following the filing of the Supplemental Amendment.

(iii) Calculation of the Total Period of Applicant Delay

In view of the PTA sheet calculations and the above remarks, Applicants have calculated a total period of Applicant Delay of 354 days, which is the sum of the following: a 95 day period, a 118 day period, a 90 day period, a 30 day period, and a 21 day period. Applicants respectfully submit that the correct period of Applicant Delay is 354 days.

C. Calculation of Correct Patent Term Adjustment Pursuant to 37 CFR §1.702(f)

As set forth in 37 CFR §1.703(f), Applicants are entitled to a period of patent term adjustment equal to the period of Examination Delays reduced by the period of Applicant Delay

(i.e., 1619 days – 354 days = 1147 days). Therefore, Applicants submit that the correct patent term adjustment for the above-referenced application is **1265 days**.

4. In accordance with 37 CFR§1.705(b)(2)(iii), Applicants submit that the present application is not subject to a terminal disclaimer.

Dated: July 15, 2010

Respectfully submitted,

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